Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the success rate of pulpectomy with CEM cement pulpotomy in primary molars; A multicenter Randomized Clinical Trial

Protocol summary

Study aim

To compare clinical and radiographic success rates of Metapex pulpectomy and Calcium-Enriched Mixture (CEM) Cement pulpotomy in primary molars with inflamed radicular pulp

Design

This is a randomized, blinded, multicenter (two universities and three operators) clinical trial with a parallel group design. The initial sample size was calculated to be 100 teeth.

Settings and conduct

This study will be conducted in the clinics of pediatric dentistry departments of Mashhad and Yazd University of Medical Sciences. Children and their parents/caregivers will be blinded. The operators can not be blinded due to the nature of the treatments. The outcome assessors and data analyzer will also be blinded. Three pediatric dentistry residents will conduct clinical treatments. Eligible teeth will be selected and after pulp exposure following caries removal the coronal pulp will be amputated. If the pulp stumps shows the evidence of inflammation, the teeth will then be definitely included in the study and will be randomly allocated into 2 intervention groups: CEM Cement pulpotomy and Metapex pulpectomy. Following pulp therapy, the teeth will be restored with stainless steal crowns and will be followed 6, 12, 18 and 24 months postoperatively.

Participants/Inclusion and exclusion criteria

Pediatric patients aged 4-9 years Primary molars with vital pulps and deep carious lesions Presence of inflamed radicular pulp after pulp amputation (sever bleeding may be present that can be controlled up to 10 minutes) Tenderness to percussion or spontaneous pain may be present

Intervention groups

CEM cement pulpotomy Metapex Pulpectomy

Main outcome variables

Clinical and radiographic success of the treated teeth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049838N1**
Registration date: **2021-01-12, 1399/10/23**
Registration timing: **retrospective**

Last update: **2021-01-12, 1399/10/23**
Update count: **0**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

Sedigheh Sabbagh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3806 7100

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-05, 1396/04/14

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the success rate of pulpectomy with CEM cement pulpotomy in primary molars; A multicenter Randomized Clinical Trial

Public title

Comparison of pulpectomy with CEM cement pulpotomy in primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric patients aged 4-9 years Primary molars with vital pulps and deep carious lesions Presence of inflamed radicular pulp after pulp amputation (sever bleeding may be present and can be controlled up to 10 min) Tenderness to percussion or spontaneous pain may be present

Exclusion criteria:

Evidence of Pulp necrosis Pathologic internal or external root resorption Pathologic mobility Pulp canal obliteration

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of teeth will be done by simple randomization method using a web-based randomization service (www.randomizer.org). The generated list of random numbers will be kept by those other than the operators.

Blinding (investigator's opinion)

Double blinded

Blinding description

Children and their parents/caregivers will be blinded, they will not know to which group they belong. The operators can not be blinded due to the nature of the treatments. The clinical outcome assessors will be those other than operators and they will be unaware of the treatment provided to each patient. The radiographic outcome assessors can not be blinded due to the nature of treatments. The data analyzer will just be informed about the aims of the research. He will not know which data set is belong to which group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah street, Goreishi building

City

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Province

Razavi Khorasan

Postal code

9138813944

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.mums.sd.REC.1394.242

Health conditions studied

1

Description of health condition studied

inflamed radicular pulp of primary molars which is the indication for pulpectomy treatment

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Clinical success rate of CEM cement pulpotomy and Metapex pulpectomy

Timepoint

6, 12 months

Method of measurement

spontaneous pain, Tenderness to percussion and palpation, gingival swelling, presence of sinus tract/fistula, pathologic mobility

2

Description

Radiographic success rate of CEM cement pulpotomy and Metapex pulpectomy

Timepoint

6, 12 months

Method of measurement

Internal root resorption, pathologic external root resorption, furcal/periapical radiolucencies, pulp canal obliteration, periodontal ligament widening, Pathologic

involvement of succedaneous tooth

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: CEM cement pulpotomy: following coronal pulp amputation, hemostasis will be attempted (up to 10 minutes), then CEM cement (BioniqueDent, Tehran, Iran) paste will be inserted to the pulp chamber to cover pulp stumps. The rest of the cavity will then be filled with light-cured resin-modified glass ionomer cement and the tooth will be restored permanently with stainless steal crown.

Category
Treatment - Other

2

Description
Intervention group: Metapex Pulpectomy: radiographic working length will be determined and radicular pulp will be extirpated. The canals will be dried with paper points. Root canals will be then filled with Metapex (Calcium Hydroxide + Iodoform) (Meta Biomed Co., Ltd, Korea). The rest of the cavity will be then filled with light-cured resin-modified glass ionomer cement and the tooth will be restored permanently with stainless steal crown.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The clinic of Pediatric dentistry department of Mashhad University of Medical Sciences

Full name of responsible person
Alireza Sarraf Shirazi

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Vakilabad Blvd

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2

Recruitment center

Name of recruitment center
The clinic of Pediatric dentistry department of Shahid Sadoughi University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
30

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

2

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
70
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Will be sent on demand of individual researchers
Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available